REMARKS

Objection to the Specification

The Examiner has objected to the specification by noting that paragraph [0025] includes a grammatical error. Applicant has amended paragraph [0025] to correct the grammatical error and requests withdrawal of the objection.

Rejections under 35 U.S.C. § 103(a)

Claims 16, 17, and 19-24

Claims 16, 17, and 19-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,077,405 (hereinafter "Haerton") in view of U.S. Patent No. 6,986,732 (hereinafter "Bui") in further view of U.S. Patent No. 6,129,702 (hereinafter "Woais").

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the applied reference (or references when combined) must teach or suggest all the claim limitations. *See* MPEP § 2143.

Applicant respectfully submits that the applied references do not satisfy these criteria.

Applicant has amended claim 16. The amendment to claim 16 is supported by the original application. No new matter has been entered.

Claim 16 recites:

> determining whether an occlusion is present in the flow path using the transient pressure differentials, the transient pressure differentials being determined when the controller component closes a valve to interrupt flow of the fluid infusate from the implantable drug pump device;
>
> determining a location of an occlusion when an occlusion is detected using the transient pressure differentials;
>
> controlling said valve disposed in said fluid path between said reservoir and said delivery site to control infusate output from said reservoir to said delivery site as a function of said transient pressure differentials across said flow restrictor, wherein the

controlling said valve automatically responds to a detection of a partial occlusion by altering a unit dose period for delivery of the fluid infusate;

communicating a signal, from implantable drug pump device to an external device, that is indicative of an amount of occlusion detected by the controller; and

communicating a signal, from implantable drug pump device to an external device, that is indicative of a location of the occlusion.

Haerten is directed to an infusion pump medical device that uses an electro-mechanical valve to control the infusion of a therapeutic agent (e.g., insulin) into a patient according to an adjustable or predetermined program. *See* col. 3, lines 10-50. The device described in Haerten is described as being capable of adapting operation of the valve to address flow rate changes due to temperature changes (or pressure changes resulting from such temperature changes). *See* col. 4, lines 25-29. The infusion pump of Haerten does not determine whether an occlusion is present in its flow path as acknowledged on page 3 of the Office Action.

The Office Action relies on Bui for the occlusion-related limitations of claim 16. Bui is related to a fundamentally different type of device. Specifically, Bui is directed to a "phacoemulsification" system that is used to ultrasonically create an incision in the cornea of a patient. The system in Bui includes irrigation functionality that is used to remove the emulsified cornea matter and to transfer away heat generated by the ultrasonic tip. *See* col. 1, lines 13-26. In such a system, the aspiration line of the irrigation functionality can be occluded by the emulsified cornea matter. To address the difficulties with occlusion of the aspiration line, the system in Bui uses a pressure sensor to determine whether to increase or decrease the speed of the pump that supplies the irrigation fluid. Col. 3, lines 34-44.

Applicant respectfully submits that Bui is non-analogous art. *See* MPEP § 2141.01(a). Specifically, Bui is not reasonably pertinent to the particular problem with which the inventor was concerned. *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). Bui merely utilizes the known relation of pressure, flow resistance, and flow rate. However, Bui is not relevant to and does not explain how to adopt such a principle to modify an infusion pump. Specifically, the operation of an infusion pump is sufficiently different than the irrigation functionality of the system in Bui that one of ordinary skill in the art would not believe that Bui would provide insight into modifying an infusion pump in an appropriate manner.

Additionally, Bui does not teach or suggest determining the "transient pressure differentials" by closing a valve "to interrupt a flow of the fluid infusate from the implantable drug pump device." Furthermore, Bui does not teach or suggest determining "a location of an occlusion when an occlusion is detected using the transient pressure differentials." In particular, there is only one location in Bui that is described as possibly being susceptible to occlusion (the aspiration line). Bui does not communicate the location of an occlusion or the amount of an occlusion in the manner recited by claim 16.

Woias discloses a dosing system for delivering a therapeutic agent to a patient. The dosing system of Woias is operated external to the patient. The dosing system in Woais does not determine whether an occlusion exists, the location of such an occlusion, or communicate the location and amount of the occlusion in the manner recited by claim 16.

Thus, the applied references (either individually or in combination) do not teach or suggest each and every limitation of claim 16. A prima facie case of obviousness has not been established for claim 16. Claims 17 and 19-24 depend from claim 16 and, hence, inherit all limitations of claim 16. A prima facie case of obviousness has not been established for these claims.

Claim 18

Claim 18 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Haerton in view of Bui in further view of Woais in further view of U.S. Patent No. 5,342,404 (hereinafter "Alt").

Claim 18 recites "wherein said unit dose periods are selected at least in part to reduce battery consumption."

The Office Action specifically relies on Alt to address the limitation of claim 18. Office Action, page 4.

Alt is directed to a device for treating ventricular tachycardia (VT) or fibrillation (VF) by applying to the patient's heart selected ones of different electrical waveforms for treatment to break the VT or VF, respectively. *See* Abstract of Alt. Alt further discloses that efficient

electrical operation of the device in Alt is achieved by treating VT and VF using different waveforms, because the VT waveform requires less energy than the VF waveform. Col. 10, lines 35-45.

This disclosure of Alt has no relevance to implantable drug pump devices or to the limitation of claim 18.

Thus, the applied references (either individually or in combination) do not teach or suggest each and every limitation of claim 18. A prima facie case of obviousness has not been established for claim 18.

Double Patenting

Claims 16-24 are rejected under the ground of non-statutory obviousness-type double patenting over claims 1-11 of U.S. Patent No. 6,620,151.

Applicant respectfully disagrees that the claims of the present application are obvious over the claims of the '151 patent. However, solely for the purpose of expediting prosecution, Applicant has submitted a terminal disclaimer. Applicant requests withdrawal of the double patenting rejection.

Conclusion

Applicant respectfully submits that the application is in condition for allowance and requests the Examiner to pass the application to issue. Applicant believes no fee is due with this response. However, if a fee is due, please charge Deposit Account No. 50-3906 from which the undersigned is authorized to draw.

Applicant does not believe that an extension of time is necessary. However, if any extension of time is necessary, Applicant hereby petitions for such extension of time and authorizes the Office to charge Deposit Account No. 50-3906 from which the undersigned is authorized to draw for the appropriate extension of time fee.

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Respectfully submitted,

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